

### **REMARKS/ARGUMENTS**

Claims 1-2, 4, 6-7, and 9-13 constitute the pending claims in the present application. Claim 7 is withdrawn from consideration as being drawn to a non-elected invention. Claims 3, 5, and 8 have been canceled without prejudice. Claims 1-2 and 11-13 have been amended. Support for the amendments is found in the specification and in the original claims. No new matter is being introduced. Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the prior Office Action.

Applicants note that the Examiner has entered the amendments filed October 3, 2003.

#### **Withdrawn objections/rejections**

Applicants note that the Examiner has withdrawn the objection of claim 6 and withdrawn the rejection of claims 5-6 in view of Applicants' arguments and amendments.

#### **Claim rejections under 35 U.S.C. 112, first paragraph**

Claims 1-2 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants respectfully traverse this rejection to the extent it is maintained over the claims as amended.

Particularly, the Office Action asserts that "although the specification discloses a single structure having the functional properties of the claimed engineered cells, the engineered cells of the rejected claims are not limited to comprising that structure."

Applicants reiterate the arguments made of record and submit that claims 1 and 2 satisfy the written description requirement without amending the claims. Nevertheless, solely to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have amended claim 1 to recite a screening assay with engineered funga cells, and amended claim 2 to incorporate the subject matter of allowable claim 8. Applicants submit that the specification

provides both working examples and sufficient description of these functional characteristics that are coupled with correlation between function and structure of the cells.

For example, the specification teaches that “[a]ny convenient host cell strain may be used provided that it can function as a host for a fungal IPC synthase gene” (e.g., page 2, lines 12-13). Furthermore, the specification describes other cells besides *S. cerevisiae* that may be used in the practice of the invention. For example, the specification teaches that “[c]onvenient hosts include fungi that are manipulatable genetically such as *S. cerevisiae* but also others such as *Candida albicans*, *Candida glabrata*, *Aspergillus* sp. or *Schizosaccharomyces pombe*” (e.g., page 2, lines 12-17). In addition, the specification amply teaches that cells comprising an *lcb1* allele and an *SLC1-1* gene, whose capability to synthesize sphingolipids depends on the addition of exogenous phytosphingosine and which are capable of sustained growth via compensatory phospholipids, can be used in the claimed screening assay (see, e.g., Examples 1-2; pages 3-6). The Examiner has offered neither art nor arguments to suggest that a person skilled in the art would not recognize this statement as true, and “what is conventional or well known ... in the art need not be disclosed in detail.” Guidelines for the Examination of Patent Applications Under 35 U.S.C. 112, ¶1, p. 1106.

For the reasons stated above and for the reasons already made of record, Applicants submit that claims 1-2 as amended fully comply with the written description requirement. One skilled in the art would reasonably conclude that Applicants had possession of the invention as claimed in claims 1 and 2 at the time of filing. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. 112, first paragraph, are respectfully requested.

Claim rejections under 35 U.S.C. 112, first paragraph

Claims 1-3 are rejected under 35 U.S.C. 112, first paragraph, because of alleged non-enablement. Applicants respectfully traverse this rejection to the extent it is maintained over the claims as amended.

Applicants reiterate the arguments made of record and submit that claims 1-3 satisfy the enablement requirement without amending the claims. Nevertheless, solely to expedite prosecution of claims directed to commercially relevant subject matter, Applicants have

amended independent claims 1 and 2 as described above, to more particularly point out the features of the claimed invention. Claim 3 has been canceled without prejudice.

Applicants submit that the specification sufficiently enables one skilled in the art to practice the invention of claims 1-2. For example, the specification sufficiently teaches how to make and use the *S. cerevisiae* (lcb1/pGPD3-SLC1-1) strain in a reproducible manner (e.g., Example 1, page 3-6). Given the detailed teachings of the specification and the knowledge in the art, one skilled in the art could readily make and use the lcb1/pGPD3-SLC1-1 yeast strain without undue experimentation.

Based on the above arguments, Applicants submit that claims 1-2 as amended comply with the enablement requirement of 35 U.S.C. 112, first paragraph. Therefore, reconsideration and withdrawal of this rejection are respectfully requested.

Claim objections

Claims 11-13 are objected to because of the recitation of "[t]he method of." Applicants have amended these claims to recite "[t]he assay of" as suggested by the Examiner.

CONCLUSION

The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Should an extension of time be required, Applicants hereby petition for same and request that the extension fee and any other fee required for timely consideration of this submission be charged to **Deposit Account No. 18-1945**.

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**Customer No: 28120**  
Docketing Specialist  
Ropes & Gray LLP  
One International Place  
Boston, MA 02110  
Phone: 617-951-7000  
Fax: 617-951-7050

Respectfully Submitted,



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David P. Halstead, Ph.D.  
Reg. No. 44,735